

**Determination of the Safety of Bayer's  
LLRICE62 event (Herbicide Tolerant)  
For Direct Use as Food and Feed or for Processing**

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**Food and Feed Safety**

The product dossier of LLRICE62 was evaluated for safety and nutritional differences compared with conventional rice. The evaluation was focused on any new or altered trait expression and change in composition and nutritional content or value relative to conventional rice. After thorough assessment, the following conclusion was made: LLRICE62 is as safe and nutritious as conventional rice for consumptions by humans and animals.

A biosafety permit for LLRICE62 and all progenies derived from crosses of the product with any conventionally bred rice for direct use was issued to Bayer CropScience, Inc. on May 16, 2012. The permit is valid for five years, subject to the terms and conditions set forth in DA Administrative Order No. 8, Series of 2002 as amended by DA Administrative Order No. 22, Series of 2007. The said LLRICE62 was included in the Approval Registry prepared by the Department of Agriculture- Bureau of Plant Industry.

*This approval is for use as food and feed or for processing LLRICE62 in the Philippines. Food and feed use of LLRICE62 and its by-products is therefore authorized as of May 16, 2012. The biosafety permit (No. 12-058) for direct use stated that "LLRICE62 and all progenies from crosses of this product except when stacked with other biotech traits has undergone satisfactory assessment and found to be as safe as conventional rice and can be a substitute for its traditional counterpart as food and feed or for processing"*

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**I. Brief Identification of the Genetically Modified Organism (Living Modified Organism)**

Designation: LLRICE62, OECD identifier ACS-OS002-5

Applicant: Bayer CropScience, Inc  
3/F Bayer House  
Canlubang, Calamba City, Laguna  
4028 Philippines

Plant Species:

Crop: Rice (*Oryza sativa.*)

Parent Material: Variety Bengal

Center of Origin: Subtropics of Southeast Asia

Toxic Factors/Allergen(s): Not commonly considered to be a food allergen

Trait Description: Tolerance to the herbicide glufosinate ammonium

Trait Introduction Method: Direct gene transfer via particle acceleration. One copy of the *bar* gene expression cassette was introduced

Donor Organism: *Streptomyces hygroscopicus*(strain HP632) is a naturally occurring common soil saprophytic bacterium

Pathogenicity: *Streptomyces hygroscopicus* is non-pathogenic and has no reported adverse effects to human and animals.

Proposed Use: For direct use as food and feed or for processing

## **II. Background Information**

Bayer CropScience, Inc. has developed a rice event with tolerance to glufosinate ammonium herbicide. The event, designated as LLRICE62, was developed to impart novel tolerance to the herbicide glufosinate ammonium which allows for the control or suppression of weeds in rice production.

On August 31, 2006, Bayer CropScience, Inc. submitted an application to the Bureau of Plant Industry (BPI) requesting a biosafety permit for direct use as food and feed or for processing under A.O. #8 for LLRICE62 which has been genetically modified for herbicide tolerance. Bayer CropScience, Inc. has provided information on the safe history of use of the crop, the source of the donor gene, the molecular characterization of the LLRICE62 event, the stability of the inserted genetic elements, characterization and expression levels of the PAT protein, safety of the PAT protein including absence of any allergenicity or toxicity characteristics, the nutrient composition of forage and grain as well as processed fractions, and overall food and feed safety of plants containing the LLRICE62 event and products derived from them. Relevant scientific publications were also supplied.

The LLRICE62 event has been evaluated according to BPI's safety assessment procedures carried out by the relevant DA agencies: Bureau of Animal Industry (BAI), Bureau of Agriculture Fisheries and Product Standards (BAFPS) and Scientific Technical Review Panel (STRP) members. The process involved an intensive analysis of the nature of the genetic modification with a consideration of general safety issues, and the toxicological and nutritional characteristics of the LLRICE62 event.

The petitioner/applicant published the said application in two (2) widely circulated newspapers (Malaya and The Daily Tribune) on December 11, 2006 for public comments/review. BPI did not receive any comments during

the 30-day comment period in regards to the LLRICE62 application for direct use as food and feed or for processing. However, outside of this comment period, the BPI received several documents opposing LLRICE62. These were forwarded to the applicant, and to the concerned STRP members who found that the proponent had fully evaluated and demonstrated the safety of the PAT protein in accordance with the internationally accepted criteria set out in the Codex Alimentarius Commission Guideline (Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, CAC/GL 45-2003).

In 2007, a case was filed by Greenpeace against the DA entitled “Declaration of Unconstitutionality of DA Administrative Order No. 8, Prohibition, Mandamus Injunction and Temporary restraining Order (TRO)”. On August 16, 2010, the Clerk of the Court of Appeals issued certification that an entry of judgment for the case had been made, and recorded in the book of entries of judgment the decision rendered by the Court of Appeals dated November 4, 2009 that has become final and executory. In view of the Court of Appeals decision dissolving the writ of preliminary injunction issued by the Regional Trial Court on Bayer’s LLRICE62 application, it is the DA Legal Division’s opinion that there is no more legal impediment to BPI processing Bayer’s LLRICE62 application.

Review of the results of evaluation by the BPI Biotech Core Team in consultation with DA-Biotechnology Advisory Team (DA-BAT) completed the approval process.

### **III. Description of Novel Protein (Introduced Traits)**

The *bar* coding sequence was isolated from *Streptomyces hygroscopicus*, a common soil bacterium that is not known to be a human or animal pathogen. The expression of the *bar* gene expressed in event LLRICE62 is regulated by a constitutive promoter. The *bar* gene encodes the phosphinotricin acetyltransferase (PAT) enzyme. The PAT protein is well-characterized in terms of its activity and substrate specificity. This enzyme acetylates glufosinate ammonium, thus in LLRICE62 plants it serves to detoxifying herbicides that contain glufosinate ammonium as the active ingredient. This acetylation activity of the PAT enzyme is highly specific.

The PAT protein belongs to a class of acetyltransferase enzymes that are common to plants and animals. There are no reports of toxicity or allergenicity associated with these proteins. The PAT enzyme expressed by LLRICE62 does not possess characteristics associated with food toxins or allergens: it shares no sequence homology with known allergens or toxins, it has no N-glycosylation sites, and it is rapidly degraded in simulated gastric and intestinal fluids.

Glufosinate ammonium plants expressing PAT proteins have been in commercial cultivation since the late 1990s. There is no evidence for any adverse effects resulting from the use of these products in food or feed.

#### **IV. Nutritional Composition (Compositional Analysis)**

Important nutritional components of rice grain were compared in samples of LLRICE62, produced both with and without treatment with glufosinate ammonium, and conventionally produced Bengal rice. Samples were analyzed for proximates, amino acids, fatty acids, micronutrients such as vitamins and minerals, and antinutrients. It was concluded that the genetic modification did not alter the nutritional composition of grain derived from LLRICE62 plants, and that food and feed derived from LLRICE62 plants is nutritionally equivalent to conventional rice.

#### **V. Anti-Nutritional Factors**

The rice bran fraction of rice grain naturally contains three types of antinutrients: phytic acid, trypsin inhibitors and lectins. With the exception of phytic acid, these antinutrients are subject to heat denaturation. Rice bran is typically subjected to heat treatment to prevent it from becoming rancid. In samples of the three rice commodities: rough rice, polished rice and rice bran, there was no difference in the phytic acid content of LLRICE62 and conventional rice, and the other antinutrients were not detectable.

#### **VI. Regulatory Decision**

After evaluation of the scientific data generated in accordance with internationally accepted standards submitted by Bayer CropScience, Inc. supporting the safety of LLRICE62, it is concluded that rice containing the LLRICE62 event is as safe as conventional rice. This conclusion applies to any rice containing the LLRICE62 event, except where it is combined with other biotech traits through conventional breeding. Rice containing the LLRICE62 event is as safe and nutritious as conventional rice and is therefore approved for direct use as food and feed or for processing.

The regulated article shall be solely for direct use as food and feed or for processing and not for field testing or propagation. Bayer CropScience shall take appropriate measures to protect human and animal health and the environment and prevent a recurrence should accidental, unintentional reproduction occurs. Bayer CropScience shall also duly inform the public of the approval for direct use by way of publishing in any one (1) of the top three (3) leading newspapers in the country that imports of this product are covered by conditions for approval as provided in Department of Agriculture Memorandum Circular No. 8, Series of 2002.